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EXAMINER

CHAPMAN, GINGER T

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/804,165

Applicant(s)

CALEFFI, LUCA

Examiner

Ginger T. Chapman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 33-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-54 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/05; 11/04; 4/04; 10/26/05; 11/12/04 and 4/23/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-32 in the reply filed on 7 June 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Accordingly, claims 33-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7 June 2006.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign mentioned in the description: **953**: "a third length of discharge duct 96", see Specification p. 21, l. 17.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character not mentioned in the description: **963**: leads to arterial outlet connection 92, see Fig. 2; note Spec. p. 21, l. 17 (953).

Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet

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submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 recites the limitation "said second expansion chamber" in lines 3-4. There is insufficient antecedent basis for this limitation in the claim.

Claim 15 recites the limitation "said first expansion chamber" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-27 and 29-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Schoendorfer et al (US 5,188,588).

With regard to claim 1, as seen in Figures 6-8, Schoendorfer et al disclose a circuit for extracorporeal blood circulation comprising: a blood withdrawal line (10b, 46b, 54b) having at least a first inlet end (40b) destined to be put in communication (80) with a patient's vascular access; at least a second outlet end (42b) destined to be connected with an inlet of a blood treatment unit (20b); and at least one pump portion (fig. 6) designed to be coupled with a pump (P1) for blood circulation in the circuit; a blood return line (53b, 48b, 10b) for returning treated blood to the patient, having: at least a first inlet end (42b) destined to be put into communication with an outlet of the treatment unit (20b); and at least a second outlet end (10a) (c. 13, l. 7) destined to connected with a patient's vascular access (80); at least one arterial chamber (64b) arranged on the withdrawal line (10b) between the pump portion (P3) and the second outlet end (22b) of the withdrawal line, and designed to contain a first blood storage volume (figs. 7 and 8); at least one venous chamber (66b) arranged on the return line (10a) and designed to contain a

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second blood storage volume (figs. 7 and 8); the two chambers being solidly joined one to the other (figs. 7 and 8).

With regard to claim 2, Schoendorfer et al disclose the two chambers (64b, 66b) are joined one to the other into an integrated structure (fig. 8) having an arterial inlet (92) and an arterial outlet (94) in fluid connection with arterial chamber (64b), and a venous inlet connection (96) and a venous outlet connection (90) in fluid connection with venous chamber (66b).

With regard to claim 3, Schoendorfer et al disclose arterial outlet and venous inlet arranged on same side of integrated structure (fig. 8).

With regard to claim 4, Schoendorfer et al disclose arterial outlet connection and venous inlet connection have each an operating axis connecting to corresponding portion of blood conveying line, the operating axes being parallel one to the other (figs. 6 and 8).

With regard to claim 5, Schoendorfer et al disclose arterial inlet connection (92) and arterial outlet (94) arranged one beside the other on same side of integrated structure (fig. 8).

With regard to claims 6-9, in Figures 2 and 4, Schoendorfer et al disclose integrated structure (16) equipped inside with at least a first duct (50) which connects a first of connection (92) with a first of the chamber (66) and a part of duct (50) passes through at least a central portion of the integrated structure (16) in which the two chambers (64, 66) are placed beside the other, and first connection is far from first chamber and placed on one side of a second of the chambers placed beside the first chamber (figs. 4 and 8).

With regard to claims 10-17, Schoendorfer et al disclose first duct (50) comprises a length (fig. 4) extending in a mainly vertical direction leading to connection (92) arranged above second expansion chamber (66) and first chamber (64) is an arterial chamber and integrated

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structure (16) is equipped inside with a second duct (48: c. 8, l. 24) which puts into fluid connection the second of said connections (96) with the first chamber (64) and a part of pathway of followed by second duct (48) is parallel to a part of pathway of first duct (50) and second duct (48) comprises a length leading to first expansion chamber (16a: c. 8, ll. 24-26) and length of second duct (48) follows a bow-shaped pathway (fig. 2) and at least one of the two chambers (64, 66) has at least an inlet opening (96) and an outlet opening (90) arranged in a lower portion of chamber (fig. 8), inlet opening (96) located slightly above outlet opening (fig. 8).

With regard to claim 18, as seen in Figure 7, Schoendorfer et al disclose chamber has inclined bottom, inlet and outlet openings placed close to upper and lower ends respectively of the inclined bottom.

With regard to claims 19 and 20, Schoendorfer et al disclose the two chambers are an integrated structure (figs. 7 and 8) having at least a deflecting element (68) designed to deviate downwards the blood flow entering a lateral inlet of at least a chamber and upper end is secured to a lateral wall of chamber and comprises a bow-shaped screen and a free lower end (70, 72) (c. 8, l. 40-43).

With regard to claims 21-23, Schoendorfer et al disclose chambers are joined one to the other into integrated structure (fig. 8) having at least a pair of pump portions (P1, P4) connected to two opposite ends of a pump portion of the return line (10a) and designed to be coupled to a pump (c. 13, ll. 4-7), pump portion of return line (10a) is arranged downstream from venous chamber (66), pump portion (p1) extends on substantially vertical plane and is arranged below (fig. 6) integrated structure (16).

With regard to claims 24-25, Schoendorfer et al disclose integrated structure (16) is equipped inside with first connection cavity (53b) putting in fluid communication at least one of the pump portion (P4) connections with a venous chamber (66b) and second connection cavity (46b) putting in fluid communication at least on the pump portion connections with a venous outlet connection (c. 13, l. 17-23).

With regard to claim 26, Schoendorfer et al disclose integrated structure (16) made of stiff material (c. 8, l. 32).

With regard to claim 27, as seen in Figure 7, Schoendorfer et al disclose chambers have substantially flattened shape and are joined one beside the other on one lateral side into an integrated structure.

With regard to claim 29, Schoendorfer et al disclose withdrawal line (10b) and return line (10a) are designed to be connected (c. 2, l. 26) with a single-needle vascular access (c. 1, l. 9; fig. 6: (80)).

With regard to claims 30-32, Schoendorfer et al disclose a disposable haematic module (26b) designed to be used on an extracorporeal blood treatment machine (fig. 6) designed to carry out haemofiltration (c. 1, l. 13).

Claims 10, 15 and 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schoendorfer et al in view of Leppert (US 4,885,001).

With regard to claims 10, 15 and 28, Schoendorfer does not expressly disclose a second venous chamber and second arterial chamber. Leppert, at c. 2, ll. 66-68 and c. 3, ll. 15-25, teaches the ability of a the volumes in second venous and arterial chamber to increase and

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decrease thereby returning blood to the patient faster in the return phase thereby speeding up flow of blood through the system thus expressing the desire and motivation for second venous and arterial chambers. As seen in Figure 1, Leppert teaches a single needle extracorporeal blood circuit having second venous and arterial chambers utilized as expansion chambers (c. 1, l. 44). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the circuit of Schoendorfer having second chambers as taught by Leppert, since Leppert states at c. 3, ll. 44-46 that the advantage making an extracorporeal blood circuit with this design is that it is possible to return blood to a patient faster than the blood is drawn from the patient.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Lindsay (US 6,306,346 B1) discloses in Figures 8 and 9 a disposable haematic module designed to be used on an extracorporeal blood circulation machine as recited in the instant claims 30-32.

Heath et al (US 4,798,090) discloses in Figures 1-3 an integrated structure (10) having arterial and venous chambers (14, 16) having flattened shape and having a bow-shaped pathway (32) with its concavity pointing upwards as recited in the instant claims 16 and 27.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571) 272-4934. The examiner can normally be reached on Monday through Friday 8:30 a.m. to 5:00 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ginger Chapman
Examiner, Art Unit 3761
08/04/06



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